CI-0012



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of

Shirley MIEKKA, Martin J. MACPHEE, William N. DROHAN, David M. MANN and Wilson BURGESS

Serial No.:

09/960,703

Filed:

September 24, 2001

For:

METHODS OF STERILIZING PREPARATIONS

OF NON-AQUEOUS SOLVENTS

: Group Art Unit: 1744

: Examiner: To be assigned

07.

INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents Washington, D.C. 20231

Sir:

Pursuant to 37 C.F.R. 1.56, the attention of the Patent and Trademark Office is hereby directed to the reference(s) listed on the attached PTO-1449. One copy of each reference is attached. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the reference(s) be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the indicated date. Applicant reserves the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be enabling for the teachings purportedly offered. This statement should not be construed as a representation that a search has been made, that information cited in the statement is considered to be and/or is material to patentability, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith. It is further understood that the Examiner will consider information that was cited or submitted to the U.S. Patent and Trademark Office in a prior application relied on under 35 U.S.C. §120. 1138 OG 37, 38 (May 19, 1992).

- X 1. This Information Disclosure Statement is being filed (i) within three months of the U.S. filing date of a U.S. application other than a CPA continued prosecution application under §1.53(d) OR (ii) within three months of the date of entry of the national stage as set forth in §1.491 in an international application OR (iii) before the mailing date of a first Office Action on the merits. No certification or fee is required. 37 C.F.R. §1.97(b).
 - 2. This Information Disclosure Statement is being filed more than three months after the U.S. filing date AND after the mailing date of the first Office Action on the merits, but before the mailing date of a Final Réjection OR Notice of Allowance OR an action that otherwise closes prosecution in the application: 37 C.F.R. §1.97(c).

180.00 C

03/27/2002 JBALIKAN 00000090 09960703

- a. I hereby state that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. 1.97(c)(1).
- b. I hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. 1.97(e)(2).
- c. Attached is our check no. ______ in the amount of \$180.00 in payment of the fee under 37 C.F.R. 1.17(p). Please credit or debit Deposit Account No. 16-0607 as needed to ensure consideration of the disclosed information. Two duplicate copies of this paper are attached.
- 3. This Information Disclosure Statement is being filed after the mailing date of a Final Rejection OR Notice of Allowance OR an action that otherwise closes prosecution in the application, but on or before payment of the Issue Fee. Attached is our check no. ____ in the amount of \$180.00 in payment of the fee under 37 C.F.R. 1.17(p). Please credit or debit Deposit Account No. 16-0607 as needed to ensure consideration of the disclosed information. Two duplicate copies of this paper are attached. 37 C.F.R. §1.97(d).
- a. I hereby state that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. 1.97(e)(1).
- b. I hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. 1.97(e)(2).
- <u>X</u> 4. The relevancy of the non-English language references can be determined from the attached abstracts.

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby $\underline{\mathbf{X}}$ made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 16-0607 and please credit any excess fees to such deposit account.

> Respectfully submitted, FLÉSHNÉR & KIM, LLP

Mark L. Fleshner

Registration No. 34,596 Donald R. McPhail

Registration No. 35,811

Date:March 25, 2002 MLF:DRM:kpc

Correspondence Address:

Chantilly, VA 20153-1200 Telephone: (703) 502-9440

P.O. Box 221200

ATTY. DOCKET NO. APPLN. SERIAL NO. CI-0012 09/960,703 F PRIOR ART CITED BY **APPLICANT APPLICANT** Shirl y MIEKKA tal. FILING DATE **GROUP** (PTO-1449) **September 24, 2001** 1744 U.S. PATENT DOCUMENTS EXAMINER *ISSUE **FILING** INITIALS *PATENT NO. DATE *INVENTOR NAME CLASS **SUBCLASS** DATE RE 23,195 02/1950 Arno Brasch 2,832,689 04/1958 Bernard E. Proctor et al. 2,920,969 01/1960 E.S. Stoddard 2,962,380 11/1960 J.H. Wertheim 3,620,944 11/1971 Keiko Tanito 3,743,480 07/1973 John D. Falk 3,779,706 12/1973 Nablo 4,136,094 01/1979 Condie 4,251,437 02/1981 Rasmussen et al. 4,282,863 08/1981 Beigler et al. 4,330,626 05/1982 Blair et al. U.S. PATENT APPLICATION PUBLICATIONS *PATENT APPLN. PUB. NO. *PUB. *APPLICANT **CLASS SUBCLASS** DATE **U.S. PATENT APPLICATIONS** *APPLN. *FILING NO. DATE *INVENTOR CLASS **SUBCLASS FOREIGN PATENT DOCUMENTS EXAMINER'S** Translation **INITIALS** PATENT NO. DATE COUNTRY **CLASS SUBCLASS** 2,056,619 10/1991 Canada 310 316 04/1989 Europe 334 679 09/1989 Europe 919 918 A2 06/1999 Europe (Abstract) 919 918 A3 06/1999 Europe (Abstract) OTHER ART (Including Author, Title, Date, Pertinent Pages, Publisher, Place of Publication, Etc.) AABB FDA Liaison Meeting, ABC Newsletter, December 12, 1997, pp. 14 Ozan Akkus et al., Fracture Resistance of Gamma Radiation Sterilized Cortical Bone Allografts, 2001, pps. 927-934, Journal of Orthopaedic Research, Vol. 19 Tikvah Alper et al., The Exceptionally Small Size of the Scrapie Agent, 1966, pps. 278-284, Biochemical and Biophysical Research Communications, Vol. 22, No. 3 **EXAMINER DATE CONSIDERED**



LIST OF PRIOR ART CITED BY APPLICANT

ATTY. DOCKET NO.
CI-0012

APPLICANT
Shirley MIEKKA et al.

FILING DATE

APPLN. SERIAL NO.
09/960,703

APPLICANT
GROUP

| Vo" | | | | Shirley MIEKKA et al. | | | | |
|-------------------|--|-------------------|-----------------------------------|--------------------------|---------------|-------------------|-------|-----------|
| (PTO-1449) | | | | FILING DATE September 24 | GROUP 1744 | | | |
| J'e | | U | .S. PATENT D | OCUMENTS | TENNE A L | The second second | - | |
| EXAUTING INITIALS | *PATENT NO. | *ISSUE DATE | *INVENTOR NAME Kotitschke et al. | | CLASS | SUBCLASS | | ING TE |
| | 4,370,264 | 01/1983 | | | | | | |
| | 4,409,105 | 10/1983 | Hayashi et al. | | | | | |
| | 4,472,840 | 09/1984 | Jefferies | | | | | |
| | 4,620,908 | 11/1986 | Van Duzer | | | | | |
| | 4,865,602 | 09/1989 | Smestad et al. | | | | | |
| | 4,933,145 | 06/1990 | Uchida et al. | | | | | |
| | 4,946,648 | 08/1990 | Dichtelmüller | et al. | | | | |
| | 4,963,356 | 10/1990 | Calenoff et al. | | | | | |
| | 5,000,951 | 03/1991 | Bass et al. | | | | | |
| | 5,106,619 | 04/1992 | Wiesehahn et | al. | | | | |
| | 5,134,295 | 07/1992 | Wälischmiller | | | | | |
| | 5,185,371 | 02/1993 | Rubinstein | | | | | |
| | • . | U.S. PATE | NT APPLICAT | ION PUBLICATI | ONS | | | |
| | *PATENT APPLN. PUB. NO. | *PUB. DATE | *AF | PLICANT | CLASS | SUBCLASS | | |
| | <u> </u> | <u> </u> | OREIGN DATENT | DOCUMENTS | | | | |
| EXAMINER'S | | | CKEIGIA PATEIAT | ATENT DOCUMENTS Trans | | lation | | |
| INITIALS | PATENT NO. | DATE | COUNTRY | | CLASS | SUBCLASS | Yes | No |
| | 11-216147 | 08/1999 | Japan (Abstrac | | | | X | |
| | 1321420-A | 07/1987 | Soviet Union (| Abstract) | | | X | |
| | WO 90/00907 | 02/1990 | PCT Int'l (Abs | • | _ | ļ | X | |
| | WO 91/16060 | 10/1991 | PCT Int'l (Abs | tract) | | | X | ļ |
| | WO 95/03071 | 02/1995 | PCT Int'l (Abs | tract) | | | X | |
| OTH | ER ART (Includi | ng Author, Ti | tle, Date, Pertir | ient Pages, Publish | er, Place of | Publication, E | Etc.) | |
| / | Tikvah Alper et a | ıl., Protection b | y Anoxia of the | Scrapie Agent and | Some DNA | and RNA Virus | ses | - |
| | Irradiated as Dry Preparations, 1968, pps. 157-166, J. Gen. Virol., Vol. 3 | | | | | | | |
| | Tikvah Alper et a | ıl., Does the Aş | gent of Scrapie I | Replicate Without N | ucleic Acid | May 20, 1967 | , | |
| | pps. 764-766, Nature, Vol. 214 | | | | | | | |
| | Tikvah Alper et al., The Scrapie Agent: Evidence Against its Dependence For Replication on | | | | | | | |
| | Intrinsic Nucleic Acid, 1978, pps. 503-516, J. Gen. Virol., Vol. 41 | | | | | | | |
| EXAMINER | EXAMINER | | I | DATE CONSIDERED | | | | |



ATTY, DOCKET NO. APPLN. SERIAL NO. CI-0012 09/960,703 LIST OF PRIOR ART CITED BY **APPLICANT APPLICANT** Shirl y MIEKKA tal. **FILING DATE GROUP** (PTO-1449) Sept mber 24, 2001 1744 U.S. PATENT DOCUMENTS **FILING** *ISSUE DATE *INVENTOR NAME **CLASS SUBCLASS** *PATENT NO. DATE Held et al. 07/1993 5,226,065 Kent 5,362,442 11/1994 Plat. et al. 5,418,130 05/1995 10/1995 Kemp 5,460,962 Sreebny et al. 04/1996 5,510,122 5,603,894 02/1997 Aikus et al. Shanbrom 5,609,864 03/1997 Ben-Hur et al. 06/1997 5,637,451 5,643,464 07/1997 Rhee et al. Horowitz et al. 5,712,086 01/1998 03/1998 Peterson 5,730,933 10/1998 Böhm et al. 5,817,528 U.S. PATENT APPLICATION PUBLICATIONS *PATENT APPLN. **SUBCLASS** *APPLICANT CLASS PUB. NO. *PUB. DATE FOREIGN PATENT DOCUMENTS Translation **EXAMINER'S SUBCLASS** CLASS INITIALS PATENT NO. DATE COUNTRY Yes X WO 00/25839 PCT Int'l (Abstract) 03/2000 X 02/2001 PCT Int'l (Abstract) WO 01/08611A1 X PCT Int'l (Abstract) WO 01/12318A1 02/2001 X PCT Int'l (Abstract) WO 01/32107A2 | 05/2001 PCT Int'l (Abstract) WO 01/32110A2 | 05/2001 OTHER ART (Including Author, Title, Date, Pertinent Pages, Publisher, Place of Publication, Etc.) S.R. Aparicio et al., Light and Electron Microscopy Studies on Homograft and Heterograft Heart Valves, 1975, pps. 174-162, J. Path, Vol. 115 J. Baksa et al., The Use of Pig's Skin (xenograft) for the Treatment of Burns, 1976, pps. 138-145, Magyar Traumatologin, Vol. 19 Michael L. Baldwin et al., Irradiation of Blood Components, 1992, pps. 10-78, American Association of Blood Banks **DATE CONSIDERED EXAMINER**



(

APPLN. SERIAL NO. ATTY, DOCKET NO. CI-0012 09/960,703 QF PRIOR ART CITED BY **APPLICANT** APPLICANT Shirley MIEKKA et al. FILING DATE **GROUP** (MAR 2 5 2002 & (PTO-1449) Sept mb r 24, 2001 1744 U.S. PATENT DOCUMENTS **FILING** EXAM *ISSUE DATE DATE **CLASS SUBCLASS** *PATENT NO. *INVENTOR NAME S INITIALS 11/1998 Ding et al. 5,837,313 03/1999 Ahlqvist et al. 5,881,534 5,981,163 11/1999 Horowitz et al. 11/1999 Noishiki 5,986,168 Burton et al. 6,046,024 04/2000 Stone et al. 6,049,025 04/2000 Yew et al. 6,066,626 05/2000 Margolis-Nunno et al. 6,087,141 07/2000 Brault et al. 6,120,592 09/2000 Deghenghi 6,159,490 12/2000 Kent 6,171,549 01/2001 U.S. PATENT APPLICATION PUBLICATIONS *PATENT APPLN. **CLASS SUBCLASS** *APPLICANT PUB. NO. *PUB. DATE **U.S. PATENT APPLICATIONS** *APPLN. *FILING CLASS **SUBCLASS** *INVENTOR NO. DATE FOREIGN PATENT DOCUMENTS Translation **EXAMINER'S** SUBCLASS CLASS Yes COUNTRY INITIALS PATENT NO. DATE X PCT Int'l (Abstract) 06/2001 WO 01/45720A1 X PCT Int'l (Abstract) WO 01/49219A1 | 07/2001 Х PCT Int'l (Abstract) WO 01/72233A1 | 10/2001 X PCT Int'l (Absrtact) 10/2001 WO 01/72244A1 \mathbf{X} WO 01/91818A1 | 12/2001 PCT Int'l (Abstract) OTHER ART (Including Author, Title, Date, Pertinent Pages, Publisher, Place of Publication, Etc.) R.H. Bassin et al., Abrogation of Fv-1bRestriction With Murine Leukemia Viruses Inactivated by Heat or by Gamma Irradiation, May 1978, pps. 306-315, Journal of Virology, Vol. 26, No. 2 Guy Beauregard et al., Temperature Dependence of the Radiation Inactivation of Proteins, 1985, pps. 117-120, Analytical Biochemistry, Vol. 150 Sandra Blakeslee, Tight Rules on Use of Organs Do Not Apply to Tissues, January 20, 2002, The New York Times Newspaper DATE CONSIDERED **EXAMINER**



APPLN. SERIAL NO. ATTY. DOCKET NO. CI-0012 09/960,703 F PRIOR ART CITED BY **APPLICANT APPLICANT** Shirley MIEKKA et al. **GROUP** FILING DATE F (PTO-1449) Septemb r 24, 2001 1744 U.S. PATENT DOCUMENTS **FILING** EXAMPLE *ISSUE DATE *INVENTOR NAME CLASS **SUBCLASS** *PATENT NO. DATE INITIALS 02/2001 Platz et al. 6,187,572 6,190,855 02/2001 Herman et al. 6,197,207 03/2001 Chapman et al. 6,203,544 03/2001 Gotzen Horowitz et al. 6,214,534 04/2001 Sowemimo-Coker et al. 6,235,508 05/2001 4,784,850 11/1998 Abraham Freeman, Jr. 4,798,611 01/1989 02/1994 Okrongly et al. 5,283,034 08/1996 Leneau et al. 5,548,066 11/1999 Odland 5,989,498 U.S. PATENT APPLICATION PUBLICATIONS *PATENT APPLN. **CLASS SUBCLASS** PUB. NO. *PUB. *APPLICANT DATE **U.S. PATENT APPLICATIONS** *APPLN. *FILING *INVENTOR **CLASS SUBCLASS** DATE NO. FOREIGN PATENT DOCUMENTS Translation **EXAMINER'S SUBCLASS CLASS** PATENT NO. DATE COUNTRY **INITIALS** OTHER ART (Including Author, Title, Date, Pertinent Pages, Publisher, Place of Publication, Etc.) Seymour S. Block, Disinfection, Sterilization, and Preservation, Fundamental Principles of Activity Principles of Antimicrobial Activity, Fourth Edition, 1991, pps. 31-33 A.J.J.C. Bogers et al., Long-Term Results of the Gamma-Irradiation-Preserved Homograft Monocusp for Transannular Reconstruction of the Right-Ventricular Outflow Tract in Tetralogy of Fallot, 1994, pps. 337-330, Thorac. Cardiovasc. Surgeon, Vol. 42 David R. Brown et al., Antioxidant Activity Related to Copper Binding of Native Prion Protein, 2001

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

DATE CONSIDERED

pps. 69-76, Journal of Neurochemistry, Vol. 76

EXAMINER





APPLN. SERIAL NO. ATTY. DOCKET NO. CI-0012 09/960,703 R PRIOR ART CITED BY **APPLICANT** APPLICANT Shirley MIEKKA tal. MAR 2 5 2002 3 FILING DATE **GROUP** &PTO-1449) **September 24, 2001** 1744 COMER ARTO Cluding Author, Title, Date, Pertinent Pages, Publisher, Place of Publication, Etc.) P. Brown, The Risk of Blood-Borne Creutzfeldt-Jakob Disease, 1999, pps. 53-59, Advances in Transfusion Safety Dev. Biol. Vol. 102 P. Brown et al., Further Studies of Blood Infectivity in an Experimental Model of Transmissible Spongiform Encephalopathy, With an Explanation of Why Blood Components Do Not Transmit Creutzfeldt-Jakob Disease in Humans, November/December 1999, pps. 1169-1178, Transfusion, Vol. 39 Paul Brown et al., Effect of Chemicals, Heat, and Histopathologic Processing on High-Infectivity Hamster-Adapted Scrapie Virus, May 1982, pps. 683-687, The Journal of Infectious Diseases, Vol. 145, No. 5 P. Brown et al., The Distribution of Infectivity in Blood Components and Plasma Derivatives in Experimental Models of Transmissible Spongiform Encephalopathy, September 1998, pps. 810-816, Transfusion, Vol. 38 D.G. Campbell et al., Sterilization of HIV With Irradiation: Relevance to Infected Bone Allografts, 1999, pps. 517-521, Aust. N.Z.J. Surg., Vol. 69 Ernest U. Conrad et al., Transmission of the Hepatitis-C Virus by Tissue Transplantation, February 1995, pps. 214-224, The Journal of Bone and Joint Surgery, Vol. 77-A, No. 2 A.S. Dagli, Correction of Saddle Nose Deformities by Coral Implantation, 1997, pps. 274-276, Eur. Arch. Otorhinolaryngol, Vol. 254 Defeng et al., Sterilization of Silver-Acidum Pipemedicum Skin for the Treatment of Burns by Radioactive Cobalt-60-. Gamma.-Ray, 1995, pps. 406 (Abstract) P. Di Simplicio et al., The Reactivity of the SH Group of Bovine Serum Albumin With Free Radicals, 1991, pps. 253-262, Free Rad. Res. Comms., Vol. 14, No. 4 R.J. Donnelly et al., Gamma-radiation of Heart Valves at 4°C; A Comparative Study Using Techniques of Histochemistry and Electron and Light Microscopy, 1973, pps. 95-101, Thorax, Vol. 28 Duane C. Eichler et al., Radiation Inactivation Analysis of Enzymes, July 15, 1987, pps. 9433-9436, The Journal of Biological Chemistry, Vol. 262, No. 20 Luanne H. Elliott et al., Inactivation of Lassa, Marburg and Ebola Viruses by Gamma Irradiation, Q Oct. 1982, pps. 704-708, Journal of Clinical Microbiology, Vol. 16, No. 4 Bradley M. Fideler et al., Gamma Irradiation: Effects on Biomechanical Properties of Human Bone-Patellar Tendon-Bone Allografts, 1995, pps. 643-646, American Journal of Sports Medicine, Vol. 23, No. Bradley M. Fideler et al., Effects of Gamma Irradiation on the Human Immunodeficiency Virus, July 1994, The Journal of Bone and Joint Surgery, Vol. 76-A, No. 7 Fields et al., Susceptibility of Scrapie Agent to Ionizing Radiation, April 5, 1969, pps. 90-91, Nature, Vol. 222 M.M. Ghosh et al., A Comparison of Methodologies for the Preparation of Human Epidermal-Dermal Composites, October 1997, pps. 390-404, Annals of Plastic Surgery, Vol. 39, No. 4 J.R.P. Gibbons et al., Effects of Gamma Irradiation on the Initial Mechanical and Material Properties of Goat Bone-Patellar Tendon-Bone Allografts, 1991, pps. 209-218, J. Orthop Res, Vol. 9, No. 2 **DATE CONSIDERED** EXAMINER

| CAPPLICANT MAR 2 5 2002 | | ATTY. DOCKET NO. CI-0012 | APPLN. SERIAL NO. 09/960,703 | | | |
|--------------------------|---|-------------------------------------|---------------------------------|--|--|--|
| | | APPLICANT Shirl y MIEKKA tal. | | | | |
| MAR 2 5 | PTO-1449) | FILING DATE S ptemb r 24, 2001 | GROUP 1744 | | | |
| ONDERAN | ON TER AND Including Author, Title, Date, Pertinent Pages, Publisher, Place of Publication, Etc.) | | | | | |
| | J.R.P. Gibbons et al., Gamma Ray Sterilisation of Homograft Valves, 1969, pps. 353-358, Bulletin De | | | | | |
| | Societe Internationale De Chirugie, No. 3 | | | | | |
| | M.J. Goertzen et al., Anterior Cruciate Ligament Reconstruction Using Cryopreserved Irradiated Bone-ACL-Bone-Allograft Transplants, 1994, pps. 150-157, Knee Surgery Sports Traumatology Arthroscopy, Vol. 2 M.J. Goertzen et al., Sterilisation of Canine Anterior Cruciate Allografts by Gamma Irradiation in Argon, March 1995, pps. 205-212, The Journal of Bone and Joint Surgery, Vol. 77-B, No. 2 Slawomir Gregorczyn et al., Strength of Lyophilized and Irradiated Cortical Bone of the Human Femur, 1995, pps. 129-133, Chir. Narz. Ruchu Ortop. Pol., Lx 2 | | | | | |
| : | | | | | | |
| | | | | | | |
| | | | | | | |
| 1 | | | | | | |
| | | | | | | |
| | D.A. Haig, Further Studies on the Inactivation of the Scrapie Agent by Ultraviolet Light, 1969, | | | | | |
| | pps. 455-457, J. Gen. Virol., Vol. 5 | | | | | |
| | F.W. Hehrlein et al., Biochemische Veränderungen an Heterologen Aortenklappentransplantaten nach (English Summary found at p. 183) | | | | | |
| | Anwendung Verschiedener Sterilisationsverfahren, pps. 1183-1185, Langenbecks Arch. Chir., Bd. 325 (Kongrebericht) | | | | | |
| | F.W. Hehrlein et al., Morphologische Utersuch | ungen an Heterologen Herzklap | pentransplantaten Unter | | | |
| | Verschiedenen Sterilisationsbedingungen, pps. | 244-251 (English Summary fou | nd at p. 250) | | | |
| | H. Hiemstra et al., Inactivation of Human Immu | inodeficiency Virus by Gamma | Radiation and its Effect on | | | |
| | Plasma and Coagulation Factors, 1991, pps. 32-39, Transfusion, Vol. 31, No. 1 | | | | | |
| | Richard Hinton et al., A Biomechanical Analysis of Solvent-dehydrated and Freeze-Dried Human Fascia Lata Allografts, 1992, pps. 607-612, The American Journal of Sports Medicine, Vol. 20, No. 5 | | | | | |
| | | | | | | |
| | B. Horowitz et al., Inactivation of Viruses in La | | | | | |
| | 1985, pps. 523-527, Transfusion, Vol. 25, No. 6 | 6 | | | | |
| | M. Horowitz, Sterilization of Homograft Ossicl | | nber 1979, pps. 1087-1089, | | | |
| | The Journal of Laryngology and Otology, Vol. | | | | | |
| | Carol House et al., Inactivation of Viral Agents | | radiation, 1990 | | | |
| | pps. 737-740, Can. J. Microbiol., Vol. 36 | <u> </u> | | | | |
| | Shinichiro Ijiri et al., Effect of Sterilization on I | Bone Morphogenetic Protein, 19 | 994, pps. 628-636, | | | |
| | Journal of Orthopaedic Research, Vol. 12 | | | | | |
| | A.S. Imamaliev et al., Biological Properties of | Bone Tisue Conserved in Plastic | c Material and Sterilized | | | |
| | With Gama Rays, 1974, pps. 129-135, ACTA, | | | | | |
| | A. Ingegneri et al., An 11-Year Assessment of 9 | | | | | |
| | 1979, pps. 304-307, Thorac. Cardiovasc. Surge | | | | | |
| | J. Jerosch et al., A New Technique for Bone Sterilization, 1989, pps. 117-120, Biomedizinische | | | | | |
| | Technik, Band 34, Heft 5 | | | | | |
| | J. Jerosch et al., Influence of Different Rehydration | Periods on the Stability and the Wa | ter Content of Bone Allografts | | | |
| | After Lyophilization, Gamma-Irradiation, and Lipid | | | | | |
| | J.D. Keathley et al., Is There Life After Irradiation? Part 2: Gamma-Irradiated FBS in Cell Culture | | | | | |
| | July/August 1993, pps. 46-52, BioPharm | | | | | |
| EXAMINER | | DATE CONSIDERED | | | | |



LIST OF PRIOR ART CITE OF APPLICANT

ATTY. DOCKET NO. CI-0012

APPLN. SERIAL NO. 09/960,703

APPLICANT

Shirley MIEKKA tal.

| | Olimby wiletton tail | | | |
|---|---|--|--|--|
| | (PTO-1449) MAR 2 5 2002 FILING DATE GROUP 1744 | | | |
| OTHER ART (Including Author, Title Date, Pages, Publisher, Place of Publication, Etc.) | | | | |
| E.S. Kempner et al., Size Determination of Enzymes by Radiation Inactivation, 1979, pps. 2-10, Analytical | | | | |
| | Biochemistry, Vol. 92 | | | |
| | L. Kerboull et al., In Vitro Study of the Influence of Avrious Conservation Methods on the Mechanical Properties of Patellar Tendon Allografts, 1991, pps. 751-762, Chirurgie, Vol. 117 A.D. Kitchen, Effect of Gamma Irradiation on the Human Immunodeficiency Virus and Human Coagulation Proteins, 1989, pps. 223-229, Vox Sang, Vol. 56 Andrezej Komender et al., Some Biological Properties of Bovine Trypsinized Fascia Xenografts, 1981, pps. 485-489, Archivum Immunologiae et Therapiae Experimentalis, Vol. 29 Andrezej Komendar et al., Some Biological Properties of Preserved Bovine Fascia Enrighed With | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | Pulverized Calf Cartilage, 1984, pps. 211-219, Archivum Immunologiae et Therapiae Experimentalis, Vol. 32 | | | |
| • | J.F. Kouvalchouk et al., The Use of Sterilized Bone Allografts in Reconstruction After Tumour Resection | | | |
| | 1986, pps. 393-401, Revue de Chirurgie Orthopedique, Vol. 72 | | | |
| | Raymond Latarjet, Inactivation of the Agents of Scrapie, Creutzfeldt-Jakob Disease, and Kuru by | | | |
| | Radiations, 1979, pps. 387-407, Slow Transmissible Diseases of the Nervous System, Vol. 2 | | | |
| | R. Latarjet et al., Inactivation of the Scrapie Agent by Near Monochromatic Ultraviolet Light, | | | |
| | September 26, 1970, pps. 1341-1343, Nature, Vol. 227 Douglas C. Lee et al., A Direct Relationship Between the Partitioning of the Pathogenic Prion Protein and Transmissible Spongiform Encephalopathy Infectivity During the Purification of Plasma Proteins, April 2001, pps. 449-455, Transfusion, Vol. 41 Susan F. Leitman, Use of Blood Cell Irradiation in the Prevention of Posttransfusion Graft-vs-Host Disease, 1989, pps. 219-232, Transfus. Sci., Vol. 10 Linberg et al., Irradiated Homologous Cartilage For Orbital Reconstruction, July 1980, pps. 457-462, | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | Ophthalmic Surgery, Vol. 11 | | | |
| | Sandra McDowell, Irradiated Cartilage, Spring 1988, pps. 14-15, Plastic Surgical Nursing A. Maeda et al., Effects of Solvent Preservation With or Without Gamma Irradiation on the Material Properties of | | | |
| | | | | |
| | Canine Tendon Allografts, 1993, pps. 181-189, Journal of Orthopaedic Research, Vol. 11 Akira Maeda et al., Solvent-dried and Gamma-irradiated Tendon Allografts in Rats, July 1998, pps. 731-736, The | | | |
| | Journal of Bone and Joint Surgery, Vol. 80-B, No. 4 | | | |
| | S. Malawski et al., The Use of Dry-Freezed Bone Grafs Sterilized by Gamma Rays in Orthopaedic Surgery, 1969, | | | |
| | pps. 61-68, Chir. Narz. Ruchu Ortop. | | | |
| | Linda Marton et al., Disinfection and Inactivation of the Human T. Lymphotrogic Virus Type III/Lymphadenopathy- | | | |
| | Associated Virus, August 1985, pps. 499-403, The Journal of Infectious Diseases, Vol. 151, No. 2 S.I. Miekka et al., New Methods for Inactivation of Lipid-enveloped and Non-enveloped Viruses, 1998, pps. 402-40 | | | |
| | | | | |
| | Haemophilia, Vol. 4 | | | |
| | Ken Nakata et al., Reconstruction of the Lateral Ligaments of the Ankle Using Solvent-dried and Gamma-Irradiated | | | |
| | Allogeneic Fascia Lata, May 2000, pps. 579-582 | | | |
| | Maria Esther Martinez Pardo et al., Clinical Application of Amniotic Membranes on a Patient With Epidermolysis | | | |
| | Bullosa, 1999, pps. 68-73, Annals of Transplantation, Vol. 4, No. 3-4 | | | |
| EXAMINER | DATE CONSIDERED | | | |

| LICTURE DRIVEN A DECUEDO A | | ATTY. DOCKET NO. CI-0012 | APPLN. SERIAL NO. 09/960,703 | | |
|----------------------------|--|--|---------------------------------|--|--|
| LIS1 | OF PRIOR ART CITED BY APPLICANT (PTO 1440) (PTO 1440) | APPLICANT Shirley MIEKKA t al. | | | |
| | (F1O-1449) | September 24, 2001 | GROUP 1744 | | |
| OTHER A | RT (Including Author, Title Cate Partner | nt Pages, Publisher, Plac | e of Publication, Etc.) | | |
| | Jan Parizek et al., Duraplasty With Pretreated Fro | reeze-Dried Sterilized Human I | Oura Mater, 1990, | | |
| | pps. 135-143, Sbor. ved. Praci LF UK Hradee Ki | | | | |
| | Jan Parizek et al., Ovine Pericardium: A New Ma | laterial For Duraplasty, 1996, p | ps. 508-513, | | |
| | J. Neurosurg., Vol. 84 | | | | |
| | Patel et al., Effect of Gamma Radiation and Ethy | ylene Oxide on Papain, 1979, p | ps. 81-83, Indian. J. Pharm. | | |
| | Sci., Vol. 41, No. 2 | Sci., Vol. 41, No. 2 | | | |
| | Z. Mark Plavsic et al., Resistance of Procine Circ | covirus to Gamma Irradiation, | April 2001, pps. 32-35, | | |
| | BioPharm | | | | |
| | L.V. Polezhaeu et al., Repair of Cranial Defects | With Regenerating Bone in Gr | afting Gamma-Irradiated | | |
| | Bone Filings, pps. 57-60 | <u>.</u> | | | |
| | Pollard, The Effect of Ionizing Radiation on Viruses, pps. 65-71 | | | | |
| | Donald J. Prolo et al., Composite Autogeneic Human Cranioplasty: Frozen Skull Supplemental With | | | | |
| il | Fresh Iliac Corticocancellous Bone, December 1984, pps. 846-851, Neurosurgery, Vol. 15, No. 6 | | | | |
| | Donald J. Prolo et al., Superior Osteogenesis in Transplanted Allogeneic Canine Skull Following Chemical | | | | |
| | Sterilization, August 1982, pps. 230-242, Clinical Orthopaedics and Related Research, No. 168 Elena Quaglio et al., Copper Converts the Cellular Prion Protein Into a Protease-resistant Species That Is Distinct From the Scrapie Isoform, April 6, 2001, pps. 11432-11438, The Journal of Biological Chemistry, Vol. 276, No. 14 | | | | |
| | | | | | |
| İ | | | | | |
| | T.J. Rasmussen et al., The Effects of 4 Mrad of Gamm | | | | |
| <u> </u> | Patellar Tendon-Bone Grafts, 1994, pps. 188-197, Th | | | | |
| | Brian D. Reid, The Sterways Process: A New Ap | pproach to Inactivating Viruses | s Using Gamma Radiation, | | |
| <u> </u> | 1998, pps. 125-130, Biologicals, Vol. 26 | | | | |
| | | S.C. Roe et al., The Effect of Gamma Irradiation on a Xenograft Tendon Bioprothesis, 1992, | | | |
| | pps. 149-154, Clinical Materials, Vol. 9 | | | | |
| 1 | Robert G. Rohwer, Estimation of Scrapie Nucleic Acid MW From Standard Curves for Virus | | | | |
| | Sensitivity to Ionizing Radiation, March 27, 198 | | | | |
| | Robert G. Rohwer, Scrapie Infectious Agent is V | Virus-like in Size and Susceptil | bility to Inactivation, | | |
| | April 12, 1984, pps. 658-662, Nature, Vol. 308 | | | | |
| | R.G. Rohwer, The Scrapie Agent: A Virus by A | any Other Name, pps. 195-232, | Current Topics in | | |
| | Microbiology and Immunology, Vol. 172 | | | | |
| | | Robert G. Rohwer et al., Scrapie-Virus or Viroid, The Case For A Virus, pps. 333-355, Laboratory of Central Nervou | | | |
| | System Studies, National Institutes of Neurological and Communicative Disorders and Stroke, National Institutes of Health | | | | |
| | Robert G. Rohwer, Virus-Like Sensitivity of the Scrapie Agent to Heat Inactivation, February 10, 1984, | | | | |
| | pps. 600-602, Science, Vol. 223 | | | | |
| EXAMINER | [| DATE CONSIDERED | | | |

| LICTO | E DDIOD ADT CITIOUS | ATTY. DOCKET NO. CI-0012 | APPLN. SERIAL NO. 09/960,703 | | |
|-----------|--|---------------------------------|--|--|--|
| | APPLICANT MAR 2 5 2002 | APPLICANT Shirley MIEKKA et al. | | | |
| | (PTO-1449) MAR 2 5 2002 | FILING DATE September 24, 2001 | GROUP 1744 | | |
| OTHER ART | T (Including Author, Title, Coto Returne | nt Pages, Publisher, Place | of Publication, Etc.) | | |
| R | Robert Sullivan et al., Inactivation of Thirty Viruses by Gamma Radiation, July 1971, pps. 61-65, | | | | |
| A | Applied Microbiology, Vol. 22, No. 1 | | | | |
| | D. Tylman, Mechanical Character of Liofilized and Sterilized by Gamma-Rays Bone Tissue, | | | | |
| 1 | 1996, pps. 229-234, Chirurgia Narzadow Ruchu I, Ortopedia Polska | | | | |
| V | W. Welch, A Comparative Study of Different Methods of Processing Aortic Homografts, 1969, | | | | |
| р | pps. 746-749, Thorax, Vol. 24 | | | | |
| J | J.M. White et al., Sterilization of Teeth by Gamma Radiation, September 1994, | | | | |
| р | pps. 1560-1567, J. Dent. Res., Vol. 73, No. 9 | | | | |
| В | Boon-Seng Wong et al., Copper Refolding of Prior Protein, 2000, pps. 1217-1224, Biochemical and | | | | |
| E | Biophysical Research Communications, Vol. 276 | | | | |
| P | Boon-Seng Wong et al., Differential Contribution of Superoxide Dismutase Activity by Prior Protein in | | | | |
| \[\bar{} | Vivo, 2000, pps. 136-139, Biochemical and Bio | physical Research Communicat | tions, Vol. 273 | | |
| E | Boon-Seng Wong et al., Prion Disease: A Loss | of Antioxidant Function? 2000, | pps. 249-252, Biochemical | | |
| a | and Biophysical Research Communications, Vol. 275 | | | | |
| | D.E. Wyatt et al., Is There Life After Irradiation? Part I: Inactivation of Biological Contaminants, June | | | | |
| 1 | 1993, pps. 34-39, BioPharm | | | | |
| | Qi Zhang et al., Ethylene Oxide Does Not Extinguish the Osteoinductive Capacity of Demineralized Bone, | | | | |
| 1 | 1997, pps. 104-108, Acta Orthop Scand, Vol. 68, No. 2 | | | | |
| S | Yongxing Zhang et al., A Comprehensive Study of Physical Parameters, Biomechanical Properties and Statistical Correlations of Iliac Crest Bone Wedges Used in Spinal Fusion Surgery, 1994, pps. 304-308, | | | | |
| S | Spine, Vol. 19, No. 3 | | | | |
| I | License Amendment and procedures for Gamma Irradiation of Blood Products, June 22, 1993, pps. 1-18, | | | | |
| l I | Dept. of Health & Human Services, Food and I | Orug Administration | | | |
| N | M.F. Alladine et al., γ-Radiation Damage to Starr-Edwards Valves, March 16, 1998, pp. 68, The Lancet, | | | | |
| I | Letters to the Editor | | | | |
| | Ch. Baquey et al., Radiosterilization of Albumin | nated Polyester Prostheses, May | / 1987, pps. 185-189, | | |
| Ī | Biomaterials, Vol. 8 | | | | |
| E | Edward H. Bedrossian, Jr., HIV and Banked Fascia Lata, 1991, pps. 284-288, Ophthalmic Plastic and | | | | |
| F | Reconstructive Surgery, Vol. 7, No. 4 | | | | |
| I | Liu Bingci, Mouse Antibody Response Following Repetitive Injections of Gamma-Irradiated Human | | | | |
| | Placenta Collagen, June 1994, pps. 100-103, Chinese Medical Sciences Journal, Vol. 9, No 2 | | | | |
| | A.A. Belov et al., The Influence of γ-Radiation on Enzyme Activity of Collalitin in the Process of Storage, | | | | |
| <u> </u> | 12/07/89, pps. 519-521, All-Union Research Institute of Textile and Haberdashery Industry, Moscow | | | | |
| | R.G. Burwell, The Fate of Freeze-Dried Bone Allografts, June 1976, pps. 95-111, Transplantation | | | | |
| 11 | Proceedings, Vol. VII, No. 2, Supplement 1 | | | | |
| EXAMINER | | DATE CONSIDERED | | | |



LIST OF PRIOR ART CITEDIES **APPLICANT** MAR 2 5 2002 FILING DATE

ATTY, DOCKET NO. APPLN. SERIAL NO. CI-0012 09/960,703

APPLICANT Shirley MIEKKA et al.

GROUP

| | | Septemb r 24, 2001 | 1744 | |
|--|---|-----------------------------------|----------------------------|--|
| OTHER ART (Including Author, Title (Cale Residuent Pages, Publisher, Place of Publication, Etc.) | | | | |
| | L. Callegaro et al., Hollow Fiber Immobilized L-Asparaginase: In Vivo and In Vitro Immunological | | | |
| | Studies, 1983, pps. 91-96, The International Journal of Artificial Organs, Vol. 6, No. 2 | | | |
| | G. Campalani et al., Aortic Valve Replacemen | t With Frozen Irradiated Homogr | rafts, 1989, | |
| | pps. 558-561, Eur. J. Cardio-thoracic Surgery, Vol. 3 | | | |
| | David T. Cheung et al., The Effect of γ-Irradia | ation on Collagen Molecules, Iso | lated α-chains, and | |
| | Crosslinked Native Fibers, 1990, pps. 581-589, Journal of Biomedical Materials Research, Vol. 24 | | | |
| | David J. Cohen et al., The Fate of Aortic Valve Homografts 12 to 17 Years After Implantation, March | | | |
| | 1988, pps. 482-484, Chest, Vol. 93, No. 3 | | | |
| | A.G. Churchalin et al., Clinical Immunosorbents Basing On Space-Network Polymers, 1998, pps. | | | |
| | 1524-1529, All Union Research Institute of Cl | nemical Reagents and Chemicals | of Special Purity, Moscow | |
| | P. De Deyne et al., Some Effects of Gamma Ir | radiation on Patellar Tendon Allo | ografts, 1991, pps. 51-62, | |
| | Connective Tissue Research, Vol. 27 | | | |
| | R.I. Vaida et al., Structural-Functional Peculiarities of Myocardial Capillaries After Resection of the Lungs, | | | |
| | 10/21/86, pps. 68-73 | | | |
| | R. Guidoin et al., A Compound Arterial Prosthesis: The Importance of the Sterilization Procedure on the Healing and Stability of Albuminated Polyester Grafts, March 1985, pps. 122-128, Biomaterials, Vol. 6 | | | |
| | | | | |
| | Ph. Hernigou et al., Radiation Sterilization of Bone and the HIV Virus, 1993, pps. 445-451, Revue de | | | |
| ļ | Chirurgie Orthopedique, Vol. 79 | | | |
| | Hsing-Wen Sung et al., Effects of Various Chemical Sterilization Methods on the Crosslinking and | | | |
| | and Enzymatic Degradation Characteristics of an Epoxy-Fixed Biological Tissue, December 1996, pps. 376-383, Sterilization of Biological Tissues | | | |
| | James R. Malm et al., An Evaluation of Aortic Valve Homografts Sterilized by Electron Beam Energy, | | | |
| | October 1967, pps. 471-477, Journal of Thoracic and Cardiovascular Surgery, Vol. 54, No. 4 James R. Malm et al., Results of Aortic Valve Replacement Utilizing Irradiated Valve Homografts, pps. | | | |
| | | | | |
| | 740-747, Annals New York Academy of Sciences W. Oh et al., Mitral Valve Replacement With Preserved Cadaveric Aortic Homografts, May 1973, pps. | | | |
| | | | | |
| | 712-721, The Journal of Thoracic and Cardiovascular Surgery, Vol. 65, No. 5 | | | |
| | K. Pietrucha, New Collagen Implant As Dural Substitute, April 1991, pps. 320-323, Biomaterials, Vol. 12 | | | |
| | | | | |
| EXAMINER | | DATE CONSIDERED | | |

| | | ATTY. DOCKET NO. CI-0012 | APPLN. SERIAL NO. 09/960,703 | |
|---|---|---------------------------------|--|--|
| PRIOR ART CITED BY APPLICANT (PTO-1449) | | APPLICANT | | |
| - 200 | APPLICANT | Shirl y MIEKKA et al. | | |
| MAR 2 5 200 | CDTO 1440) | FILING DATE | GROUP | |
| <u>\</u> &\ | | September 24, 2001 | 1744 | |
| CONTRACTOR OF THE PARTY OF THE | (Including Author, Title, Date, Pertine | | | |
| | Maria Raptopoulou-Gigi et al., Antimicrobial Pro | oteins in Sterilised Human Mil | k, January 1, 1977, | |
| | pps. 12-14, British Medical Journal, Vol. 1 | | | |
| | Edward A. Rittenhouse et al., Sterilization of Aortic Valve Grafts for Transplantation, July 1970, pps. | | | |
| | 1-5, Aortic Valve Grafts for Transplantation, Archives of Surgery, Vol. 101, No. 1 | | | |
| | H. Sato et al., Sterilization of Therapeutic Immunoadsorbents by Ionizing Radiation, | | | |
| | 1986, pps. 131-136, The International Journal of | | | |
| | Richard A. Smith et al., Gamma Irradiation of H | IV-1, 2001, pps. 815-819, Jour | nal of Orthopaedic | |
| | Research, Vol. 19 | | | |
| | Barbara Lüssi-Schlatter et al., Die Antimikrobiel | | | |
| | Gamma-Strahlen, Pharmazeutisches Institut der Galenische Abteilung | Eidgenössischen Technischen l | Hochschule Zürich | |
| | Martindale's Extra Pharmacopoecia, Glucose p. | 1265; prior art | | |
| | The Merck Index, Eleventh Edition Glucose pp. | 4353-4354, prior art | <u>,</u> | |
| ø | G.L. Moore et al., Effects of 4000 Rad. Irradiation | on on the In Vitro Storage Prop | perties of packed Red Cells, | |
| | Nov-Dec 1985, pps. 583-585, Final Rept., Pub. In Transfusion, Vol. 25, No 6 (Abstract) | | | |
| | Shcheglova et al., The Effect of the Power of Gamma-Radiation on the Radiation Dose in the | | | |
| | Sterilization of Drugs, 1984, pps. 730-732, Khim-Farm Zh, Vol. 18, No. 6 (Abstract) | | | |
| | G.A. Yarygina, Dose Rate Effect on Survival of Microorganisms Used As Test-Cultures in Radiation | | | |
| P | Sterilization of Medical Products, 1973, pps. 32 | -39, Radiats. Tekh., No. 9 (Abs | stract) | |
| <u>'</u> | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | 70. | | | |
| | | | <u> </u> | |
| | | | | |
| ! | | | | |
| | | | | |
| EXAMINER | | DATE CONSIDERED | | |